NEW HHS REGULATIONS WILL REQUIRE STATES TO PREVENT TOBACCO SALES TO MINORS

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On January 19, HHS published new regulations to encourage the States to enforce their laws prohibiting the sale and distribution of tobacco products to persons under the age of 18. The regulations implement a law Congress passed in 1992 known as the "Synar amendment," which requires States to enact and enforce such laws as a condition of receiving federal substance abuse block grant funds. As directed by Congress in the 1992 statute, these regulations will be administered by the Substance Abuse and Mental Health Services Administration ("SAMHSA").[1/]

What the Synar amendment requires. The Synar amendment imposes funding conditions designed to encourage the States to enforce their laws prohibiting the sale and distribution of tobacco products to persons under the age of 18. The conditions became applicable in most States beginning with FY 1994.[2/]

Under the Synar amendment, each State must (1) have in effect a law prohibiting the sale or distribution of tobacco products to any individual under the age of 18; (2) enforce that law "in a manner that can reasonably be expected to reduce the extent to which tobacco products are available to individuals under the age of 18"; (3) annually conduct random, unannounced inspections to ensure compliance with such law; and (4) submit annually to the Secretary of HHS a report describing the State's activities and plans, and the extent of success the State has achieved.

If the Secretary determines that a state has not complied with these requirements in the fiscal year preceding the fiscal year for which a substance abuse block grant is sought, the Secretary is directed to withhold grant funds by specified percentages.

The new SAMHSA rules. The new SAMHSA rules do three things. *First*, they require each State to have in effect a law prohibiting the sale and distribution of tobacco products to persons under the age of 18. § 96.130(b). *Second*, they establish a "performance standard" that each State must achieve within "several years," and they require each State to negotiate and achieve "interim performance targets." § 96.130(g).

1/ The HHS rules were published in 61 Fed. Reg. 1492. The Synar amendment is codified as Section 1926 of the Public Health Service Act (42 U.S.C. 300x-26).

2/ Under the rules, the "first applicable fiscal year" was FY 1994 for all States except those that did not convene a regular legislative session in FY 1993 or FY 1994. § 96.130(a). For those States, the "first applicable fiscal year" was FY 1995. All references in this memorandum to FY 1994 through FY 1997 should be understood as references to FY 1995 through FY 1998 for those states.

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Third, the rules require the State to conduct inspections to determine whether it is moving toward compliance with the performance standard. §§ 96.130(c) & (d).

Under the rules, each State must submit an annual report to the Secretary describing its activities, its plans and the extent of its success. § 96.130(e). The Secretary may withhold substance abuse block grant funds from States that do not show "substantial compliance" with the negotiated interim performance targets or the ultimate performance standard. § 96.130(h)(3) and (i). States may use block grant funds to pay for the inspections required by the rules. § 96.130(j); 61 Fed. Reg. 1500.

Performance standards. The rules require each State to ensure a specified level of compliance with its minimum sales-age law within "several years." To be in compliance at the end of that timeframe, the State must ensure that its retailers refuse to sell to minors at least 80 percent of the time, as measured by inspections required by the rules. In the terms used by the rule, this standard means that each State must demonstrate an "inspection failure rate" that does not exceed 20 percent. § 96.130(g).

The rules apply to "any location which sells at retail or otherwise distributes tobacco products including (but not limited to) locations that sell such products over-the-counter or through vending machines." § 96.130(a). The rules do not say what "several years" means. SAMHSA makes clear, however, that the period will start to run from FY 1997 and that the exact timeframe may differ from State to State. Those States that have the farthest to go will be given the most time. 61 Fed. Reg. 1498. The exact timeframe "will be negotiated with each State." *Id.* at 1499.

Interim performance target. In the meantime, the rules require each State to reach agreement with HHS on an "interim performance target" for each fiscal year (beginning with FY 1997 for most States) that will move the State in the direction of the 20-percent failure rate goal. § 96.130(g). SAMHSA says that the target level negotiated with each State for each fiscal year "should demonstrate each State's commitment to * * * showing immediate and sustained progress toward meeting the 20 percent performance objective." 61 Fed. Reg. 1498.

The results of the inspections conducted during FY 1996 (for most States) will serve as the "base line" for negotiating state-specific interim performance targets for FY 1997 and subsequent fiscal years. SAMHSA encourages the States to complete these inspections in time to permit negotiations for the FY 1997 grant application. 61 Fed. Reg. 1499.

Inspections. Under the rules, random, unannounced inspections of outlets where tobacco products are sold or distributed are to be used to measure the level of compliance with a State's minimum sales-age law.

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In the first and second applicable fiscal years (for most States, FY 1994 and FY 1995), and in subsequent fiscal years, each State must conduct annually "a reasonable number of random, unannounced inspections of outlets to ensure compliance * * * and begin to implement any other actions which the State believes are necessary to enforce the [minimum sales-age] law." § 96.130(c). In most States this requirement is moot because the second applicable fiscal year (FY 1995) has already ended. This requirement is pertinent only to States for which the second applicable fiscal year is FY 1996.

In the third and fourth applicable fiscal years (for most States, FY 1996 and 1997), each State must conduct "annual, random, unannounced inspections of both over-the-counter and vending machine outlets." § 96.130(d)(1). The inspections must be conducted in such a way as to provide a "probability sample" of outlets and the sample must reflect "the distribution of the population under age 18 throughout the State and the distribution of the outlets throughout the State accessible to youth." § 96.130(d)(2). As noted, States are expected to conduct these inspections using a probability sample of outlets during FY 1996 for purposes of negotiating the first "interim performance target" for FY 1997.

SAMHSA describes possible sampling methodologies in the preamble to the rules, making clear that only outlets "accessible to youth" should be inspected. 61 Fed. Reg. 1497-98. The agency states that, following the publication of the rule, the Center for Substance Abuse Prevention (CSAP) will provide to the States "technical assistance and further guidance on state-of-the-art inspection processes, including guidelines, training and technical assistance." 61 Fed. Reg. 1494.

Reports. The rules require each State to submit annually to the Secretary with its application a report including:

(1) a detailed description of the State's activities to enforce its minimum sales-age law during the fiscal year preceding the fiscal year for which that State is seeking the grant;

(2) a detailed description regarding the overall success the State has achieved during the previous fiscal year in reducing the availability of tobacco products to individuals under the age of 18, including the results of the unannounced inspections required by the rules (for which the results of over-the-counter and vending machine outlet inspections shall be reported separately);

(3) a detailed description of how the unannounced inspections were conducted and the methods used to identify outlets;

(4) the strategies to be utilized by the State for enforcing such law during the fiscal year for which the grant is sought; and

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(5) the identity of the agency or agencies designated by the Governor to be responsible for the implementation of the requirements of the Synar amendment.

The public will be afforded an opportunity to comment on the report prior to its submission to the Secretary. § 96.130(f); 61 Fed. Reg. 1497.

Penalties. Beginning with the second applicable fiscal year, the Secretary will make a determination, before making a block grant to a State for that fiscal year, "whether the State reasonably enforced its law in the previous fiscal year" pursuant to the rules. § 96.130(h). The Secretary cannot make a positive determination, except in extraordinary circumstances, unless a State is in "substantial compliance" with the negotiated target for the fiscal year. § 96.130(h)(3)(ii). If the Secretary determines that a State is not in substantial compliance, the Secretary will reduce the amount of the State's substance abuse prevention and treatment grant as specified in the Synar amendment.

Funding. The rules permit the States to use funds from the primary prevention setaside of their SAPT Block Grant allotment under 45 CFR 96.142(b)(1) for developing the sample design and conducting the inspections required by the rules. § 91.130(j). SAMHSA also will allow States to use funds from the CDC's Preventative Health and Health Services Block Grant. 61 Fed. Reg. 1500.

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Throughout the preamble to the final rules, SAMHSA repeatedly stresses the flexibility that its rules ensure the States in working to reduce the sale and distribution of tobacco products to persons under the age of 18. Several points should be noted in this regard:

Additional laws not required. SAMHSA specifically says in the preamble to the rules that the *only* law a State must have on the books to be in compliance is a minimum sales-age law. 61 Fed. Reg. 1495-96. A State is *not* required to ban or restrict vending machines, self-service displays or tobacco product sampling, or establish licensing systems for tobacco product retailers.

"Sting" operations presumptively required. Although SAMHSA says that its rules do not require "stings" to be used to fulfill the inspection requirement, the agency also says that it knows of no valid alternative and notes that its compliance levels are based on the "sting" methodology. Nevertheless, SAMHSA indicates that it would permit another enforcement method to be used if a State can justify it. 61 Fed. Reg. 1493.

Moreover, a State is not required to allow private entities to conduct "sting" operations. SAMHSA expects the States (1) to ensure that unannounced inspections are

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conducted in a "fair, consistent, unbiased, planned manner," (2) to ensure that retailers will be protected against entrapment and (3) to take precautions to protect minors used in "stings." 61 Fed. Reg. 1495-97.

Statewide uniformity permitted. SAMHSA specifically says that its rules "neither prohibit the States from preempting, nor require them to preempt, local initiatives on youth access to tobacco products." However, SAMHSA does encourage the States to allow localities *either* to enact stricter laws *or* to enforce state laws more rigorously. 61 Fed. Reg. 1497.

States to designate responsible agency. SAMHSA does not specify that any particular agency within a State must implement the Synar amendment but expects the Governor of each State to designate "the most appropriate agency to assume lead responsibility" for implementing the requirements of the rules. 61 Fed. Reg. 1496-97.

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